



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

m34467

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
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WARNING LETTER

February 28, 2000

00-SWR-WL-37/07

**Certified Mail
Return Receipt Requested**

Larry Cousar
Head of Service
Diagnostic Imaging
601 Carnahan Drive
Maumelle, AR 72113

Re: Field Test No. GI62676

[REDACTED]
[REDACTED]
Room No. R & F 2
Manufacturer: Shimadzu
Control Serial No. 0162087103
Model No. GSC-95 WT

Dear Mr. Cousar,

On February 10, 2000, a representative from the Food and Drug Administration, conducted a field test on the above referenced x-ray equipment. This system, installed by your firm on November 6, 1999 as reported by Form FDA 2579, D319695, was tested to determine its compliance with applicable portions of the Performance Standards for Diagnostic X-ray Equipment, Title, 21, Code of Federal Regulations (CFR), Part 1020. Analysis of the data obtained indicates that the following item was not in compliance with the standard as follows:

Undertable Fluoroscopic

X-ray production was possible with the primary protective barrier in the park position (outside of the primary x-ray beam). This is in violation of 21 CFR 1020.32(a).

In accordance with provisions of 21 CFR, Parts 1003 and 1004, as the responsible manufacturer/assembler, it is requested that you investigate the cause of this noncompliance as soon as possible. If it is due to improper assembly or installation, or caused in any way by the factory based manufacturer, the regulations require that the noncompliance be corrected without charge to the user by either repairing the system, replacing it, or refunding the cost (if caused by the factory based manufacturer, you should notify him of the noncompliance) and arrange for corrective action at no cost to the owner.

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If the noncompliance is due to normal wear and tear, unwarranted user abuse, improper maintenance by the user, or improper repair, and if you can clearly explain and provide evidence which demonstrates the validity of this conclusion, then you are not required to correct the noncompliance at no charge to the owner.

Please report to this office within 15 days of receipt of this letter the causes for noncompliant performance and corrective actions taken. The corrective action should be submitted as a VOLUNTARY CORRECTIVE ACTION PLAN (CAP) that you followed to make the corrections. Any documentation, such as service order, etc., should include at least the following: date of service, type of service, and model and serial number of the certified components which required service in order to bring the system into compliance. Your CAP should also include formulas and calculations, or a copy of the manufacturer's installation procedure for the certified component corrected.

If special parts are required to be ordered, thus delaying completion of your planned corrective action beyond 15 days, you should submit a copy of the parts supplier's invoice verifying that the order has been accepted and the projected date for delivery of parts to you. In this case, your corrective actions are expected within 30 days of receipt of this letter unless otherwise precluded by parts delivery.

As you are probably aware, under Federal Law, an assembler is a manufacturer of diagnostic x-ray systems. The installation of a noncompliant x-ray system is a violation of the Food, Drug, and Cosmetic Act. An assembler who installs a noncompliant x-ray system may, therefore, be liable to civil penalty enumerated in the Act. In order to protect yourself from the penalties, your firm should make every effort to assure that every installation results in performance which complies with all requirements of the diagnostic x-ray performance standard.

Your response to this letter may be directed to Deborah M. McGee, Radiation Specialist, at Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, TX 75247. If you have any questions regarding results of the referenced field test, or related to technical matters, you may contact Ms. McGee by telephoning (214) 655-8100 x138.

Sincerely,

 *Acting RFDD*

for Edward R. Esparza
Regional Food and Drug Director